



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM:**

To: Rita Kumar

From: Jennifer Urbanski, Ph.D.

*Jm 2/6/13*

Date: 2/6/13

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 406524

Decision no.: 470090

Submission no: 924318

Action code: R350

Product Name: TC 303

EPA Reg. No or File Symbol: 499-540

Formulation Type: aerosol

Ingredients statement from the label with PC codes included: dinotefuran, 044312 (0.25%); pyriproxyfen, 129032 (0.1%); prallethrin, 128722 (0.05%)

Application rate(s) of product and each active ingredient: up to 20 oz product/2625 ft<sup>2</sup> (=0.0015 g/ in<sup>2</sup>)

**I. Action Requested:** Review efficacy data to support the addition of bed bugs (adults and eggs) and ticks to the label and to support the proposed labeling claim "Kills hatching flea eggs for up to 1 year".

**II. Background:** Studies were provided to present evidence of efficacy against bed bugs, ticks, and fleas

**III. MRID Summary:**

48950001. E.S. Snell, T. Smith, and B. Garrett. Evaluation of the Efficacy of Ultracide IIA Carpet Spray v.2 When Applied as Direct Spray Applications to Wild Strain Bed Bugs (*Cimex lectularius*). May 26, 2010.

(1) GLP or non-GLP? Non-GLP

(2) State the purpose and briefly summarize the methods and results: The purpose of this study was to determine the efficacy of Ultracide IIA Carpet Spray v.2 (same % a.i.s as TC 303) when applied as a direct spray application to adult Cooper 2 wild strain bed bugs (*Cimex lectularius*). Two sets (treated and control) of four replicates of ten beg bugs per replicate were placed in small chambers (2.4 in<sup>2</sup>). For the treatment group, spray applicators were placed 12 inches from the chambers; bed bugs were sprayed for 1 second (=5.1g/spray; application rate equivalent to 2.125 g/ in<sup>2</sup>) and transferred to clean containers 1 hour later. Knockdown, mortality and survival were recorded post-treatment at 30 min and at 1, 2, 4, 24 and 48 hours for both the treatment and control groups. There was 100% mortality after 30 minutes of exposure in the treatment group. Control mortality remained at an acceptable level.

(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials: Data support the use of 499-540 to kill adult bed bugs by direct spray at a rate of 2.125 g/ in<sup>2</sup>.

(4) Is the study acceptable or not? Acceptable

48950002. W. Donahue, Jr. Efficacy Evaluations of Ultracide IIA Carpet Spray Against Brown Dog Tick, *Rhipicephalus sanguineus* and Lone Star Tick, *Amblyomma americanum* in the Laboratory. September 13, 2010.

(1) GLP or non-GLP? Non-GLP



**(2) State the purpose and briefly summarize the methods and results:** The purpose of this study was to determine the efficacy of Ultracide IIA Carpet Spray (same %a.i.s as TC 303) when applied as a direct spray application to adult brown dog ticks, *Rhipicephalus sanguineus* and lone star ticks, *Amblyomma americanum*. Two sets (treated and control) of five replicates of each tick species (number of ticks per replicate was not reported in MRID; reviewer contacted the registrant and determined that there were between 9-20 individuals per replicate, with between 48-97 total individuals tested per treatment) were placed in 8 oz Solo cups; treatment groups were sprayed with 2.4 grams of product per replicate and transferred to clean containers five minutes after treatment. Knockdown was recorded at 5, 15, 30, and 45 minutes and at 1, 2 and 4 hours; mortality was recorded at 24 hours. Greater than 90% knockdown was reported for *Rhipicephalus sanguineus* at 5 minutes and for *Amblyomma americanum* at 30 minutes. Mortality was 100% after 24 hours for both species. Control mortality remained at zero for the length of the experiment.

**(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials:** The application rate (2.4 g/8 oz Solo cup) was much greater than the labeled application rate ( $=0.0015 \text{ g/in}^2$ ). If the size of the Solo cup was reported, data from the study would support the use of 499-540 to kill adult brown dog ticks and lone star ticks by direct spray at a rate of 2.4 g/[insert size of Solo cup]].

**(4) Is the study acceptable or not?** Partially acceptable

**48950003. E.S. Snell, et al. Efficacy of Whitmire Micro-Gen Ultracide IIA Carpet Spray v.2 When Applied as Residual Treatments to Unpainted Wood and Mattress Ticking for the Control of Bed Bugs (*Cimex lectularius*). June 27, 2010.**

**(1) GLP or non-GLP?** Non-GLP

**(2) State the purpose and briefly summarize the methods and results:** A study was conducted to test the residual efficacy of Ultracide IIA Carpet Spray v.2 (same % a.i.s as TC 303) against adult Cooper 2 wild strain bed bugs (*Cimex lectularius*) when applied as a residual spray application (1 or 28 days) to unpainted wood or mattress ticking. Two sets (treated and control) of four replicates of ten bed bugs per replicate were placed under cartridges placed upon treated or untreated 4"x4" mattress ticking or unpainted wood paneling allowed to sit for 1 or 28 days. Each treated surface was sprayed at a rate of  $9.04 \text{ g/ft}^2$  ( $=0.063 \text{ g/in}^2$ ) and allowed to dry. Bed bugs were exposed to treated surfaces either 1 or 28 days after treatment for two hours before being moved to clean containers. Mortality and knockdown were recorded at 30 minutes, 1, 2, 4, and 24 hours, then daily. Exposure of bed bugs to 1-day-old treated wood panels did not result in acceptable mortality (85% on day 11 at which point the control mortality reached 18%). Exposure of bed bugs to 1-day-old treated mattress ticking resulted in  $\geq 90\%$  mortality by day 3 (control mortality remained below 10% throughout the experiment). Exposure of bed bugs to 28-day-old treated wood panels and mattress ticking did not result in acceptable mortality (51% on day 6 for wood panels [20% control mortality] and 13% on day 6 for mattress ticking [18% control mortality]).

**(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials:** Data support the use of 499-540 to kill adult bed bugs on treated mattress ticking at a rate of  $0.063 \text{ g/in}^2$  for up to one day after the treatment dries; in other words, the data support the use of the product to kill adult bed bugs. However, residual control was not demonstrated in this study.

**(4) Is the study acceptable or not?** Partially acceptable

**48950004. E.S. Snell, et al. Efficacy of Ultracide IIA Carpet Spray v.2 When Applied as Direct Spray Applications to Susceptible and Wild Strain Bed Bug (*Cimex lectularius*) Eggs. February 1, 2011.**

**(1) GLP or non-GLP?** Non-GLP

**(2) State the purpose and briefly summarize the methods and results:** The purpose of this study was to determine the efficacy of Ultracide IIA Carpet Spray v.2 (same %a.i.s as TC 303) when applied as a direct spray application to Cooper 2 wild strain and susceptible lab strain bed bug eggs (*Cimex lectularius*), aged 2-3 days or 5-6 days. For wild and lab strain eggs aged either 2-3 days or 5-6 days, two sets (treated and control) of four replicates of ten bed bug eggs per replicate were used. For each treatment group replicate, eggs were sprayed for one second with an average of 4.5 g product (size of treatment area is unknown) then immediately transferred to clean containers. The number of hatched and unhatched eggs, then the number of alive, knocked down, and dead nymphs were recorded daily. Wild strain: For the eggs that were 2-3 days old at the time of application, maximum hatch percentage occurred at 6 days after treatment at which 98% of the control eggs and 28% of the treated eggs had hatched. Of the eggs that hatched, by 8 days after treatment 3% of control nymphs and 82% of treated nymphs were dead. In other words, treating 2-3 day old eggs by direct spray resulted in 95% mortality of eggs/nymphs by 9 days after treatment, while control eggs/nymphs had 5% mortality across the same time period. For the eggs that were 5-6 days old at the time of application, maximum hatch percentage occurred at 6 days after treatment at which 100% of the control eggs and



20% of the treated eggs had hatched. Of the eggs that hatched, by 7 days after treatment 5% of control nymphs and 100% of treated nymphs were dead. In other words, treating 5-6 day old eggs by direct spray resulted in 100% mortality of eggs/nymphs by 7 days after treatment, while control eggs/nymphs had 5% mortality across the same time period.

Susceptible strain: For the eggs that were 2-3 days old at the time of application, maximum hatch percentage occurred at 9 days after treatment at which 93% of the control eggs and 0% of the treated eggs had hatched. Of the eggs that hatched, by 11 days after treatment 0% of control nymphs were dead (there were no treatment nymphs). In other words, treating 2-3 day old eggs by direct spray resulted in 100% mortality of eggs/nymphs, while control eggs/nymphs had 7% mortality across 9 days. For the eggs that were 5-6 days old at the time of application, maximum hatch percentage occurred at 8 days after treatment at which 93% of the control eggs and 0% of the treated eggs had hatched. Of the eggs that hatched, by 11 days after treatment 0% of control nymphs were dead (there were no treatment nymphs). In other words, treating 5-6 day old eggs by direct spray resulted in 100% mortality of eggs/nymphs, while control eggs/nymphs had 7% mortality across 11 days.

**(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials:** The application rate ( $1.125 \text{ g/in}^2$ ) was much greater than the labeled application rate ( $=0.0015 \text{ g/in}^2$ ). Note that the size of the treated cardboard was not reported initially (see attached registrant email). Data from the study support the following claims at an application rate of  $1.125 \text{ g/in}^2$ : "Aids in preventing bed bug hatch" and "Kills bed bugs when they hatch".

**(4) Is the study acceptable or not?** Acceptable

**48950005. W.A. Donahue, Jr. Efficacy Evaluations of Dinotefuran Aerosol (FC 230-069, TC-303) Against Brown Dog Tick, *Rhipicephalus sanguineus* and Lone Star Tick, *Amblyomma americanum*, in the Laboratory. July 8, 2011.**

**(1) GLP or non-GLP?** Non-GLP

**(2) State the purpose and briefly summarize the methods and results:** A study was conducted to test the residual efficacy of TC 303 against to adult brown dog ticks, *Rhipicephalus sanguineus*, and lone star ticks, *Amblyomma americanum*, when applied as a residual spray application (1, 28, 84, 182, and 252 days after application) to unpainted wood or ceramic tiles. For each substrate, two sets (treated and control) of five replicates of each tick species (number of ticks per replicate was not reported in MRID; reviewer contacted the registrant and determined that there were between 2-10 individuals per replicate (mean=7), with between 22-50 total individuals tested per treatment) were placed on either 6"x6" panels of unpainted wood or ceramic tile; ticks were exposed for the duration of the experiment. Application rates were  $0.2 \text{ g/in}^2$  for lone star ticks and  $0.25 \text{ g/in}^2$  for brown dog ticks on wood, and  $0.07 \text{ g/in}^2$  for lone star ticks and  $0.08 \text{ g/in}^2$  for brown dog ticks on ceramic. Knockdown was recorded at 5, 15, 30, and 45 minutes and at 1, 2, and 4 hours; mortality was recorded at 24, 48, 72, and 120 hours. Greater than 90% mortality was reached for the following: lone star tick at 24 hours after exposure to wood aged 1 day and at 24 hours after exposure to ceramic aged 1, 28, 84, 182, and 252 days; and brown dog tick at 24 hours after exposure to wood aged 1 day, at 72 hours after exposure to wood aged 28 days, at 24 hours after exposure to ceramic aged 1, 28, and 84 days, and at 48 hours after exposure to ceramic aged 252 days. Control mortality remained at acceptable levels throughout the course of the experiment.

**(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials:** Data from the study supports the use of 499-540 to control adult brown dog ticks and lone star ticks on non-porous surfaces for up to 84 days at a rate of  $0.08 \text{ g/in}^2$ .

**(4) Is the study acceptable or not?** Partially acceptable

**48950006. A.G. Appel. Evaluation of Aged Deposits of Nylnar and Pyriproxyfen Against Larval Cat Fleas, *Ctenocephalides felis* Bouche. December 16, 2010.**

**(1) GLP or non-GLP?** Non-GLP

**(2) State the purpose and briefly summarize the methods and results:** A study was conducted to test the residual efficacy of three pyriproxyfen products against larval cat fleas. Only the two products relevant to this action will be discussed here, a 0.1% and a 0.05% pyriproxyfen aerosol. Carpet circles were treated at rates of 20 oz product [or water for controls]/2625  $\text{ft}^2$  and stored for 1, 28, 56, 112, 210, or 365 days (6 replicates per treatment per time period). Fifteen second instar flea larvae were placed onto each piece of carpet and stored in an incubator in complete darkness for thirty days after which they were transferred to a freezer for 24 hours and the number of emerged adult fleas was recorded. For both treatments at every carpet aging interval tested, no adults emerged ( $=100\%$  flea larvae mortality). However the control larvae had a high level of average mortality as well (75%



mortality averaged across all periods of aging; 1 day aged: 85% mortality; 28 days aged: 87% mortality; 56 days aged: 49% mortality; 112 days aged: 77% mortality; 210 days aged: 90% mortality; 365 days aged: 65% mortality).

**(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials:** Given the high level of control mortality, it cannot be determined whether the high level of efficacy observed was due to product application or environmental factors. Therefore, this study cannot be used on its own to support the claim that the product kills hatching flea eggs up to 1 year.

**(4) Is the study acceptable or not?** Supplemental

#### IV. RECOMMENDATIONS:

(a) What pests/label claims may be added to the label based on the submitted or cited data? Adult bed bugs (see f (3) for acceptable bed bug egg/nymph claims) and adult lone star and brown dog ticks

(b) Throughout label, delete the general tick claim. Instead, tick claims and directions for use text throughout the label must specify lone star and brown dog ticks. For a general tick claim, testing must be done on the blacklegged tick as well.

(c) The currently labeled rate (20 oz/2625 square feet=0.0015 g/in<sup>2</sup>) is much greater than the rates tested. The following rates are supported for this product based on the data submitted: 0.063 g/in<sup>2</sup> for adult bed bugs and 1.125 g/in<sup>2</sup> for bed bug eggs, and 0.08 g/in<sup>2</sup> for adult lone star and brown dog ticks.

(d) The data submitted do not support the extension of flea egg control to 1 year.

(e) Lone star and brown dog tick data indicate that the product provides residual efficacy for these species on non-porous surfaces only.

(f) Labeling revisions:

1) Change "Kills adult and immature fleas, bed bugs and ticks" to read something similar to "Kills adult bed bugs, ticks, and adult and immature fleas." The current statement incorrectly implies that the product kills immature ticks (not tested) and bed bug eggs (only aids in egg hatch prevention).

2) Change "Kills hatching flea eggs for up to 1 year" to read "Kills hatching flea eggs for up to 7 months".

3) Change "Kills bed bugs and their eggs" to read "Kills bed bugs". The following claims may be added to accurately represent the bed bug data submitted: "Aids in preventing bed bug hatch" and "Kills bed bugs when they hatch".

4) Change "Kills ticks on contact" to read "Kills ticks and bed bugs by contact".

5) On page 2, change the last sentence in the first paragraph to reflect comments 3 and 4.

6) In the bed bugs section on page 2, add "Kills bed bugs by contact" or something similar.

7) In the ticks section on page 2, change "Apply to infested areas..." to read "Apply to infested nonporous areas..."

(g) Note to label reviewer: Study rates were determined by weighing the aerosol cans before and after treatment. The acceptable application rates noted above were calculated by dividing the difference in the can weight before and after treatment by the size of the insect containers. However, according to both the study reports and the attached registrant email, areas larger than just the test container were treated by directing the spray in a slow sweeping motion at 12 inches per second. Therefore the weight difference in the cans indicates the amount that actually hit the treatment containers plus the amount that fell outside of the containers. In other words the acceptable application rates above are likely an overestimation of the amount of product needed for acceptable efficacy; unfortunately the amount of product actually contacting the insect containers is unknown, and therefore the acceptable rates listed above are on the conservative side. To better serve the user, it is recommended that additional information be added to the directions for use that indicate exactly how the product is to be applied based on the efficacy report protocols (in a sweeping motion at a speed of 12 inches per second).